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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/816,225 | 03/26/2001 | Peter Hawkins | 109068 | 5800 |

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EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/08/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/816,225

Applicant(s)

HAWKINS ET AL.

Examiner

Pensee T. Do

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 112, 2nd paragraph.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 9-13.Claim(s) withdrawn from consideration: 1-8, 15-26.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

ADVISORY ACTION

Amendment Entry & Claim Status

The after-final amendment filed on July 17, 2003 has been acknowledged and entered as paper no. 16.

Claims 9-13 are pending. Claims 1-8, 15-26 were canceled.

Withdrawn Rejection(s)

Rejection under 35 USC 112, 2nd paragraph is withdrawn herein.

Response to Arguments

The arguments filed on July 17, 2003 have been considered but not found persuasive.

Applicants argue that claim 9 recites a coil in addition to a phase-locked loop. There is no suggestion or disclosure in either Rapoport or Kritz et al. of a phase-locked loop connected to a tuned circuit, which is exposed to a magnetic field generated by a coil.

Kritz teaches an LC circuit in which a coil was a part. Rapoport teaches a device which comprises a first electrical conductor which can be a coil. The device further comprises a means for applying a known electromagnetic signal to the first electrical conductor to provide a change in which can be measured to indicate the presence of the substance of interest. Such means is equivalent to the "driver" of the claimed invention and which also is equivalent to the phase-locked loop because the claim recites that a phase-locked loop comprises a driver.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694).

Kritz teaches a method of detecting an analyte comprising the steps of providing a sample comprising a marker, a binder (recognition element), said marker having material comprising an externally, inductively detectable relative magnetic permeability constant of at least about 600, said recognition element binds to or competes for binding with the analyte, said marker and said recognition element induce in a transducer comprising a coil a first inductance value when said analyte is absent from said sample and a second inductance value when said analyte is present in said sample. The recognition element (binder) is immobilized to a matrix (substrate) – see col. 6, lines 36-37. The sample containing the analyte and marker are added to the carrier. A competition or a sandwich reaction formed. The reaction was placed in a measuring coil and inductance changes noted. The inductance change in turn affected either the resonance frequency for an LC-circuit in which the coil was a part, or the balancing expressed as a voltage response, in a Maxwell Bridge in the coil was a part. The relationship between the change of resonance frequency in Hz, or the voltage difference in mV, is a linear relationship against the number of particles in the

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measuring solution, expressed as iron concentration. The molecular layer (recognition element) comprises an antibody/antigen and the second molecules are antigens or antibodies. (see col. 3, line 10-col. 4, lines 47; col. 5, line 10-col. 6, line 42; col. 9, lines 1-4).

However, Kritz does not teach measuring the difference in resonant frequency when the substrate is exposed to a magnetic field and when the substrate is not exposed to the magnetic field; a solenoid coil.

Rapoport teaches a method for detecting in a sample a substance that responds to an applied magnetic field, such as paramagnetic substance. The sample is placed in an applied magnetic field, and the effect of the sample on a performance characteristic of a first electrical conductor is measured by the first measuring means and the value is displayed and/or optionally inputted to a data storage and analysis means. Subsequent measurements of this same performance characteristic of the first electrical conductor are made over time, either continuously or at pre-determined intervals. The performance characteristics are inductance, capacitance, etc. (See col. 3, lines 35-37). It is also desirable to compare the effect of the sample on the conductor in the presence of the applied magnetic field with the effect of the sample on the conductor in the absence of the applied magnetic field. (see col. 3, lines 20-26). Rapoport teaches a solenoid coil (figure 1).

It would have been obvious to one of ordinary skills in the art to measure the performance characteristic such as inductance of the sample in the presence and absence of the applied magnetic field as taught in Rapoport in the method of Kritz

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because that way the two measurements can be compared, taking into consideration the calibrations necessary to account for the differences, if any, in the performance characteristic of the first and second conductors. The corrected difference between the two measurements is then a function solely of the presence of a substance in the sample, which responds to the applied magnetic field.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694) further in view of Houghton et al. (US 5,679,342).

Kritz and Rapoport have been discussed above.

However, Kritz and Rapoport fail to teach a plastic strip as the substrate.

Houghton et al. teaches an assay wherein the receptor layer is immobilized on a matrix/solid support such as plastic strips, microliter plates, or any surface onto which antigen may be immobilized. (See col. 19, lines 45-51).

It would have been obvious to one of ordinary skills in the art that using matrix/solid support such as plastic strips is well known in the art. Thus, one of ordinary skills in the art would find it obvious to use plastic strips as taught by Houghton in the modified method of Kritz and Rapoport since Kritz suggested that the receptors are immobilized to a matrix and it is well known in the art that matrix for immobilizing receptor can be plastic strips for these plastic strips are polymers with compatible functional groups that immobilize the receptors securely on the strips and do not interfere with the molecular interaction of the receptor and the target analyte.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
September 4, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641